REMARKS

The Office Action mailed March 3, 2009, has been received and reviewed. Each of claims 1-26 and 28-34 stands rejected. Claims 1, 9, 12, 21, 23, and 29 have been amended herein. Claims 16 and 26-28 have been canceled. Care has been exercised to introduce no new subject matter. Reconsideration of the above-identified application in view of the above amendments and the following remarks is respectfully requested.

Rejections based on 35 U.S.C. § 101

Claims 12-28 are rejected under 35 U.S.C. 101 based on Supreme Court precedent and recent Federal Circuit decisions. Independent claims 12 and 23, from which claims 13-15, 17-22, and 24-25 (claims 16 and 26-28 are canceled) depend either directly or indirectly, have been amended to more clearly recite that the claims are tied to one or more computer processors. As such, Applicants submit that independent claims 12 and 23 are tied to a particular apparatus and thus recite patentable subject matter. Accordingly, Applicants respectfully request withdrawal of the 35 U.S.C. § 101 rejection of claims 12 and 23.

Further, Applicants submit that claims 13-15, 17-22, and 24-25 are also tied to a particular apparatus for at least the reason of their dependency on independent claims 12 and 23. Applicants respectfully request withdrawal of the 35 U.S.C. § 101 rejection of claims 13-15, 17-22, and 24-25.

Rejections based on 35 U.S.C. § 103

A). Applicable Authority

Title 35 U.S.C. § 103(a) declares, a patent shall not issue when "the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." The Supreme Court in Graham v. John Deere counseled that an obviousness determination is made by identifying: the scope and content of the prior art; the level of ordinary skill in the prior art; the differences between the claimed invention and prior art references; and secondary considerations. *Graham v. John Deere Co.*, 383 U.S. 1 (1966). To support a finding of obviousness, the initial burden is on the Office to apply the framework outlined in *Graham* and to provide some reason, suggestion, or motivation either in the prior art references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the prior art reference, or to combine prior art reference teachings, to produce the claimed invention. See, *Application of Bergel,* 292 F. 2d 955, 956-957 (1961). Recently, the Supreme Court elaborated, at pages 13-14 of the *KSR* opinion, that "it will be necessary for [the Office] to look at interrelated teachings of multiple [prior art references]; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by [one of] ordinary skill in the art, all in order to determine whether there was an apparent reason to combine the known elements in the fashion claimed by the [patent application]." *KSR v. Teleflex,* 127 S. Ct. 1727 (2007).

B). Claims 1-22 and 29-34

Claims 1-22 and 29-34 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rosenfeld et al. (U.S. Patent No. 6,804,656, hereinafter "Rosenfeld") in view of Shen (Pre-

Grant Publication No. 2003/0212580, hereinafter "Shen"). As the Rosenfeld and Shen references, either alone or in combination, fail to teach or suggest all of the features of the rejected claims, as amended herein, Applicants respectfully overcome this rejection, as hereinafter set forth.

Independent claim 1, as currently amended, generally recites a system for analyzing clinically related data. The system includes a first interface to a clinical data store storing clinically related data; a second interface to a knowledge base; and an inference engine. The inference engine communicates with the clinical data store via the first interface and with the knowledge base via the second interface. The inference engine is configured to selectively perform a comparative analysis of the clinically related data against the knowledge base. The inference engine is further configured to project a facility-wide outcome that predicts an operational effect of altering a guideline or a policy being used in a clinical facility or organization based on the comparative analysis, and to quantify an opportunity for improvement when the altered guideline or policy is utilized in the clinical facility or organization.

In contrast, Rosenfeld describes providing continuous, expert network critical care services from remote locations. By Rosenfeld a command center is provided at a remote location at which a doctor is located. *Rosenfeld* at col. 4, lines 53-57. A group of intensive care units (ICU) at disparate locations are provided with cameras and monitoring equipment such that patient data and communications are established between the command center and each of the ICUs. *Id.* at col. 4, lines 57-65. Clinical data is transmitted to the command center to allow the doctor to monitor and manage multiple patients at disparate ICUs from a single location. *Id.* at col. 5, lines 10-13. The clinical information is also submitted to a relational database that includes standardized guidelines for patient care, algorithms to support the intensive care

regimen, order writing software, and knowledge-based algorithms that key the doctor to engage in preventative actions. *Id.* at col. 5, lines 13-24. Thus, a single doctor is able to manage multiple patients at various locations by being provided with the clinical information at a single location and is assisted in identifying issues by algorithms that analyze the clinical data transmitted from the patients' ICUs. *Id.* at col. 13, lines 36-43.

As such, Rosenfeld does not disclose the inference engine of Applicants' independent claim 1, as amended herein. Rosenfeld describes a remote care network that provides data analysis, data presentation, productivity tools, and an expert knowledge base that enables a single doctor to manage multiple patients (*Rosenfeld* at col. 4, lines 8-13), however such a remote care network does not teach or suggest projecting a facility-wide outcome that predicts an operational effect of altering a guideline or a policy being used in a clinical facility or organization, as recited in independent claim 1. The relational database of Rosenfeld only provides guidelines and algorithms for use in the care of patients (Rosenfeld at col. 5, lines 10-22) and as such, is not useable to predict operational effects of altering a guideline or policy being used by a clinical facility or organization.

Further, Rosenfeld fails to teach or suggest an inference engine quantifying an opportunity for improvement if an altered guideline or policy is used in a clinical facility or organization, as recited in claim 1. For example, following Applicants' amended independent claim 1, the effects of altering a pharmaceutical guideline in a clinical facility might be quantified to determine that by altering the guideline 49 lives and $432,000 might be saved over current practices. *See Applicants' Specification* at ¶ [0021]. Although Rosenfeld discusses a relational database, it is respectfully submitted that Rosenfeld fails to teach or suggest

quantifying opportunities for improvement that result if an altered guideline is used in a clinical facility, as in independent claim 1, as amended herein.

The Office Action also cites Shen in support of Rosenfeld. Shen describes management of information flow and workflow in medical imaging services. *Shen* at ¶ [0037]. By Shen, various data items are collected throughout a patient's course of treatment by a medical imaging facility. *See id. generally.* A performance metrics module manipulates the data to calculate various flow metrics related to workflow and information flow to provide objective statistics that are useable to analyze the interaction of the workflow process with the information flow process. *Id.* at ¶ [0045]. An analysis tools module is also provided to perform practical and business performance analysis of the overall processes. *Id.* at ¶ [0046]. Using these modules outcome metrics for performance measurements are generated such that diagnostic, clinical, service, and financial outcomes for the medical imaging facility can be quantified and analyzed. *Id.* at ¶¶ [0071]-[0076]. Further, risk assessment and utilization assessments of testing procedures can also be quantified. *Id.* at ¶¶ [0059] and [0102]. Additionally, patient data may be compared to medical guidelines to aid in determining a course of patient care. *Id.* at ¶ [0085].

Shen also describes that organizational benchmarks and goals may be changed such that the changed goals and the effects thereof may be compared to the collected data. *Id.* at ¶ [0109]. Organizational process analysis is also described as allowing simulation and prediction of modified process outcomes with the new organizational goals. *Id.* at ¶ [0133].

As such, Shen does not cure the deficiencies of Rosenfeld. Shen fails to teach or suggest the inference engine of Applicants' independent claim 1. As recited by Applicants' claim, the inference engine provides a projection of a facility-wide outcome that predicts an operational effect of altering a guideline or policy in a clinical facility based on an analysis of the

clinically related data and a clinical guideline and quantifies opportunities for improvement would result if the altered guideline or policy is used in the clinical facility. Thus, a future facility-wide outcome is projected based on an alteration of a guideline. For example, where a guideline that provides that patients having a symptom A are to receive drug X is altered to provide that patients having symptom A are now to receive drug Y instead, the projection might show that patient mortality will decrease and that a cost savings might be experienced because drug Y is less expensive than drug X.

In contrast, Shen merely describes changing benchmarks and organizational goals to simulate and predict process outcomes based on those goals. Shen, however, does not teach or suggest altering guidelines or policies being used in a clinical facility. Guidelines and policies are not equivalent to goals and benchmarks. In this regard, guidelines and policies instruct how things or processes are carried out while goals and benchmarks only measure an outcome of an event.

Further, the outcomes referred to by Shen are not equivalent to the facility-wide outcomes described by Applicants' claim. The outcomes of Shen include diagnostic outcomes (e.g. patient and physician feedback, text accuracy, and subsequent treatments instructed by the tests, *Shen* at ¶ [0072]), clinical outcomes (e.g. patient symptom and changes feedback, functional measurements and changes from testing over time, clinical events, *Id.* at ¶ [0073]), service outcomes (e.g. customer satisfaction, *Id.* at ¶ [0074]), and financial outcomes (e.g. whether and how much reimbursement was received, *Id.* at ¶ [0075]). These outcomes are described by and are based on past or current data and are actual outcomes that have occurred. For example, a financial outcome might be that the imaging facility was not reimbursed for a service because a patient had no insurance and did not pay their bill. In contrast, the facility-

wide outcomes recited by Applicants include outcomes, such as financial, operational, or clinical outcomes, that are not actual outcomes, but rather possible future outcomes that might occur if the guideline or policy alteration is implemented.

Additionally, Shen does not teach or suggest quantifying opportunities for improvement that might result when such an altered guideline or policy is implemented. For example, as described above, an implementation of an altered guideline for the use of short-acting nifedipine might be quantified to indicate that 49 lives and $432,000 might be saved. Shen, on the other hand, fails to teach or suggest altering guidelines or policies and further, does not describe quantifying opportunities for improvement that might result therefrom.

The Office Action also states that an apparatus must be distinguished from the prior art in terms of structure rather than function alone. Applicants respectfully submit that the inference engine of independent claim 1, as amended, must perform the actions of communicating, performing, projecting, and quantifying as described in the claim. As such, these actions define the structure of the inference engine that must be present to perform the actions in as much as the structure and function of the inference engine can be separated.

As such, Applicants respectfully submit that independent claim 1, as amended herein, is not obvious over Rosenfeld in view of Shen. Accordingly, Applicants respectfully request the 35 U.S.C. § 103 rejection of independent claim 1 be withdrawn.

Each of claims 2-11 depends, either directly or indirectly, from independent claim 1. Thus, Applicants respectfully submit that Rosenfeld and Shen, either alone or in combination, fail to teach or suggest all of the features of dependent claims 2-11 for at least the above-cited reasons. Accordingly, Applicants respectfully request withdrawal of the U.S.C. § 103(a) rejection thereof.

With respect to independent claim 12, independent claim 12, as currently amended, recites one or more similar features to those of independent claim 1, such as selectively performing a comparative analysis, projecting a facility-wide outcome that predicts operational effects of altering a guideline or policy, as well as quantifying opportunities for improvement that result from implementing the altered guideline or policy. As such, the remarks provided above with respect to independent claim 1 apply equally to independent claim 12.

Independent claim 12 has also been amended to recite a key performance indicator that is indicative of a financial, operational, or clinical metric for operation of a clinical facility and is compared to the knowledge base for comparative analysis. Rosenfeld and Shen do not describe employing a key performance indicator to provide a comparative analysis as is recited by Applicants' independent claim 12.

As such, Applicants respectfully submit that independent claim 12, as amended, is not obvious over Rosenfeld in view of Shen. Accordingly, Applicants respectfully request the 35 U.S.C. § 103 rejection of independent claim 12 be withdrawn.

Each of claims 13-15 and 17-22 depends, either directly or indirectly, from independent claim 12. Thus, Applicants respectfully submit that Rosenfeld and Shen, either alone or in combination, fail to teach or suggest all of the features of dependent claims 13-15 and 17-22 for at least the above-cited reasons. Accordingly, Applicants respectfully request withdrawal of the U.S.C. § 103(a) rejection thereof.

Turning now to independent claim 29, independent claim 29, as currently amended, recites one or more similar limitations to those of independent claims 1 and 12 and as such, the remarks provided above with respect to independent claims 1 and 12 apply equally to independent claim 29.

As such, Applicants respectfully submit that independent claim 29, as amended herein, is not obvious over Rosenfeld in view of Shen. Accordingly, Applicants respectfully request the 35 U.S.C. § 103 rejection of independent claim 29 be withdrawn.

Each of claims 30-34 depends, either directly or indirectly, from independent claim 29. Thus, Applicants respectfully submit that Rosenfeld and Shen, either alone or in combination, fail to teach or suggest all of the features of dependent claims 30-34 for at least the above-cited reasons. Accordingly, Applicants respectfully request withdrawal of the U.S.C. § 103(a) rejection thereof.

C.) Claims 23-28

Claims 23-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Shen. As the Shen reference fails to teach or suggest all of the features of the rejected claims, as amended herein, Applicants respectfully overcome this rejection, as hereinafter set forth.

Independent claim 23, as currently amended, recites, in part, a computer-implemented method of generating an analytic report. A comparative analysis of clinically related data against a selected guideline, policy or procedure is performed to provide an indication as to whether the selected guideline, policy or procedure has been attained by a medical facility. A second guideline, policy, or procedure and an alteration thereof is received. The alteration includes altering a procedure for providing a drug to a patient, providing surgery to a patient, and discharging a patient from a clinical facility. The altered second guideline, policy, or procedure and the clinically related data corresponding with the plurality of patients are used to perform a predictive analysis that projects an operational, financial, or other facility-wide outcome that predicts an operational effect of implementing the altered second selected guideline, policy, or procedure in a clinical facility or organization. Opportunities for

improvement that result from altering the guideline, policy, or procedure are quantified. The clinically related data is updated after an implementation of the altered second selected guideline to determine whether a patient outcome or cost has improved or declined.

Shen does not teach or suggest each of the features of independent claim 23 for at least the above-noted reasons with respect to independent claims 1, 12, and 29. Additionally, independent claim 23 has been amended to include updating the clinically related data after implementation of an altered guideline, policy, or procedure. Although Shen discusses that patient data may be compared to medical guidelines to aid in determining a course of patient care, it is respectfully submitted that Shen fails to teach or suggest updating clinically related data after implementation of an altered guideline, policy, or procedure to determine whether a patient outcome or cost has improved or declined.

For at least the above reasons, Applicants respectfully submit that independent claim 23, as amended herein, is not obvious over Shen. Accordingly, Applicants respectfully request the 35 U.S.C. § 103 rejection of independent claim 23 be withdrawn.

Each of claims 24 and 25 depends, either directly or indirectly, from independent claim 23. Thus, Applicants respectfully submit that Shen fails to teach or suggest all of the features of dependent claims 24 and 25 for at least the above-cited reasons. Accordingly, Applicants respectfully request withdrawal of the U.S.C. § 103(a) rejection thereof.

CONCLUSION

For at least the reasons stated above, claims 1-15, 17-25, and 29-34 are now in condition for allowance. Applicants respectfully request withdrawal of the pending rejections and allowance of the claims. If any issues remain that would prevent issuance of this application, the Examiner is urged to contact the undersigned – 816-474-6550 or areed@shb.com (such communication via email is herein expressly granted) – to resolve the same. The Commissioner is hereby authorized to charge any amount required to Deposit Account No. 19-2112.

Respectfully submitted,

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